DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 884

[Docket No. 97P–0350]

Medical Devices; Reclassification and Codification of Home Uterine Activity Monitor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it has issued an order in the form of a letter to GE Marquette Medical Systems, Inc., reclassifying from class III to class II (special controls) the Corometrics Model 770 Home Uterine Activity Monitoring System for use in women with a previous preterm delivery to aid in the detection of preterm labor. Accordingly, the order is being codified in the Code of Federal Regulations. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a guidance document that will serve as the special control for this device.

DATES: This rule is effective [*insert date 30 days after date of publication in the* **Federal Register**]. The reclassification was effective January 5, 2001.

FOR FURTHER INFORMATION CONTACT: Colin M. Pollard, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1180.

SUPPLEMENTARY INFORMATION:

I. Background (Regulatory Authorities)

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94–295), the

Safe Medical Devices Act of 1990 (the SMDA) (Public Law 101–629), and the Food and Drug Administration Modernization Act of 1997 (the FDAMA) (Public Law 105–115), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), generally referred to as preamendments devices, are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976, generally referred to as postamendments devices, are classified automatically by statute (section 513(f) of the act) into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until: (1) The device is reclassified into class I or II; (2) FDA issues an order classifying the device into class I or II in accordance with new section 513(f)(2) of the act, as amended by the FDAMA; or (3) FDA issues an order finding the device to be substantially equivalent, under section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously offered devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR part 807 of the regulations.

A preamendments device that has been classified into class III may be marketed, by means of premarket notification procedures, without submission of a premarket approval application

(PMA) until FDA issues a final regulation under section 515(b) of the act (21 U.S.C. 360e(b)) requiring premarket approval.

Reclassification of postamendments devices is governed by section 513(f)(2) of the act. This section provides that FDA may initiate the reclassification of a device classified into class III under section 513(f)(1) of the act, or the manufacturer or importer of a device may petition the Secretary of Health and Human Services (the Secretary) for the issuance of an order classifying the device in class I or class II. FDA's regulations in § 860.134 (21 CFR 860.134) set forth the procedures for the filing and review of a petition for reclassification of such class III devices. In order to change the classification of the device, it is necessary that the proposed new class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

The FDAMA added a new section 513(f)(2) to the act that addresses classification of postamendments devices. New section 513(f)(2) of the act provides that, upon receipt of a "not substantially equivalent" determination, a 510(k) applicant may request FDA to classify a postamendments device into class I or class II. Within 60 days from the date of such a written request, FDA must classify the device by written order. If FDA classifies the device into class I or II, the applicant has then received clearance to market the device and it can be used as a predicate device for other 510(k)'s. It is expected that this process will be used for low risk devices. This process does not apply to devices that have been classified by regulation into class III, i.e., preamendments class III devices, or class III devices for which a PMA is appropriate.

Under section 513(f)(3)(B)(i) of the act, formerly section 513(f)(2)(B)(i) of the act, the Secretary may, for good cause shown, refer a petition to a device classification panel. If a petition is referred to a panel, the panel shall make a recommendation to the Secretary respecting approval or denial of the petition. Any such recommendation shall contain: (1) A summary of the reasons for the recommendation, (2) a summary of the data upon which the recommendation is based,

and (3) an identification of the risks to health (if any) presented by the device with respect to which the petition was filed.

II. Regulatory History of the Device

On August 15, 1997, FDA filed the reclassification petition submitted by GE Marquette Medical Systems, Inc., requesting reclassification of the Corometrics Model 770 Home Uterine Activity Monitoring System from class III to class II. FDA consulted with the Obstetrics and Gynecology Devices Panel (the Panel). During an open public meeting on October 7, 1997, the Panel recommended that FDA reclassify from class III to class II the Model 770 Home Uterine Activity Monitoring System for use in women with a previous preterm delivery to aid in the detection of preterm labor. The Panel also recommended patient registries, bench testing, consensus standards, and clinical validation studies as special controls.

FDA considered the Panel's recommendations and tentatively agreed that the generic type of device, home uterine activity monitor, for use in women with a previous preterm delivery to aid in the detection of preterm labor, be reclassified from class III to class II. Subsequently, in the **Federal Register** of July 30, 1999 (64 FR 41435), FDA issued the Panel's recommendation for public comment.

After reviewing the data in the petition and presented before the Panel, and after considering the Panel's recommendation and the comments, FDA, based on the information set forth, issued an order to the petitioner on January 5, 2001, reclassifying the Model 770 Home Uterine Activity Monitoring System, and substantially equivalent devices of this generic type, from class III to class II.

Accordingly, as required by § 860.134(b)(6) and (b)(7) of the regulations, FDA is announcing the reclassification of the generic Home Uterine Activity Monitor from class III into class II. The special control for this device will be a guidance document entitled "Class II Special Controls Guidance Document for Home Uterine Activity Monitors." The guidance document addresses labeling, patient registries, design controls, consensus standards, and pre-clinical and clinical testing.

In addition, FDA is issuing the notice to codify the reclassification of the device by adding new § 884.2760.

III. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this reclassification is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Enforcement Act of 1996 (Public Law 104–121), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4)). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety and other advantages, distributive impacts, and equity). The agency believes that this reclassification action is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, this final rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Reclassification of the device from class III to class II will relieve all manufacturers of the device of the cost of complying with the premarket approval requirements in section 515 of the act. Because reclassification will reduce regulatory costs with respect to this device, it will impose no significant economic impact on any small entities, and it may permit small potential competitors to enter the marketplace by lowering their costs. The agency therefore certifies that this final rule will not have a significant economic impact on a substantial number of small entities. In addition, this final rule action will not impose

costs of $100 million or more on either the private sector or State, local, and tribal governments in the aggregate, and therefore a summary statement or analysis pursuant to section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

V. Paperwork Reduction Act of 1995

FDA concludes that this final rule contains no information that is subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995. The special controls do not require the respondent to submit additional information to the public.

VI. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

List of Subjects in 21 CFR Part 884

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 884 is amended as follows:

PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

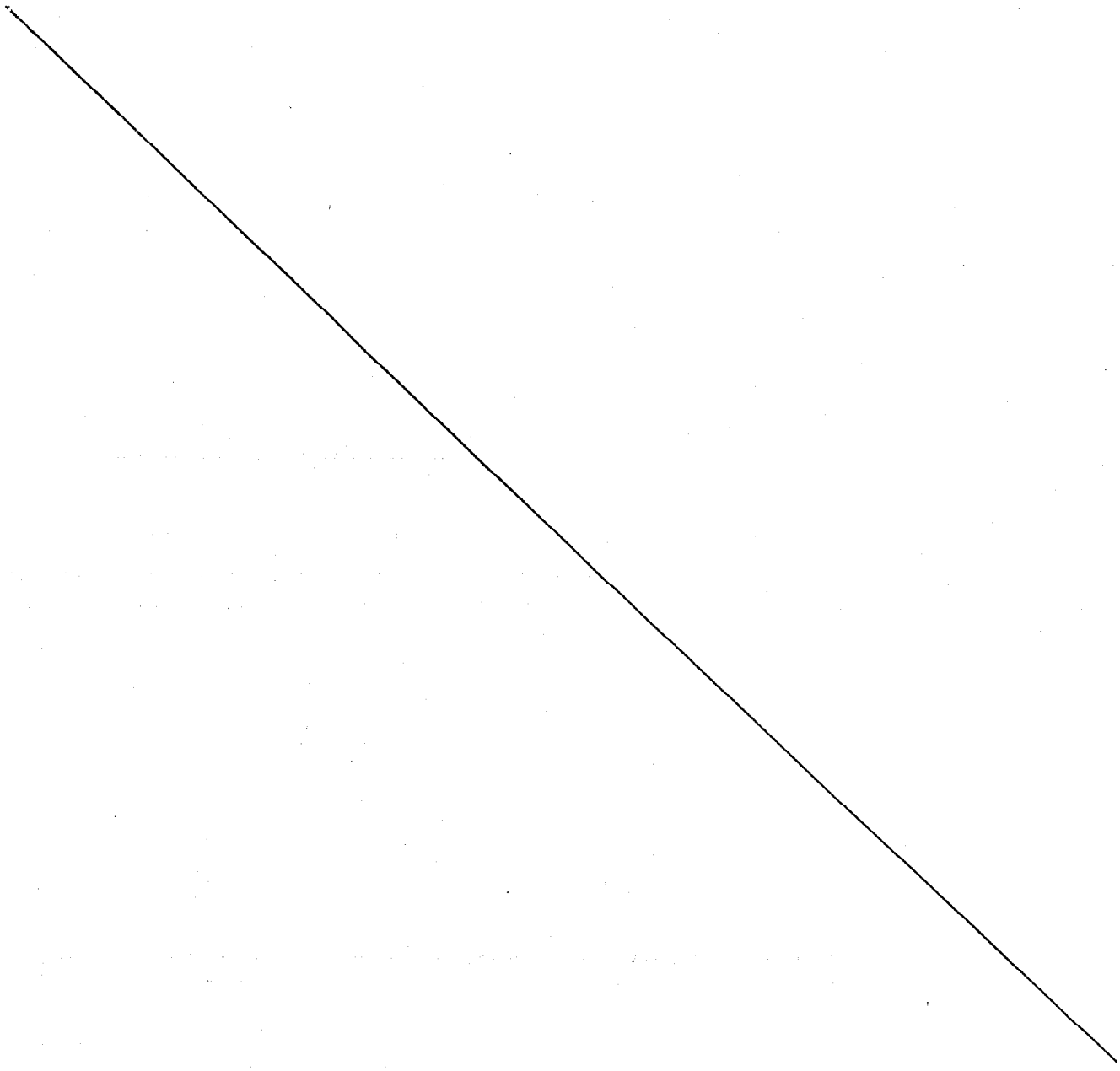
1. The authority citation for 21 CFR part 884 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 884.2730 is added to subpart C to read as follows:

§ 884.2730 Home uterine activity monitor.

(a) *Identification.* A home uterine activity monitor (HUAM) is an electronic system for at home antepartum measurement of uterine contractions, data transmission by telephone to a clinical setting, and for receipt and display of the uterine contraction data at the clinic. The HUAM system comprises a tocotransducer, an at-home recorder, a modem, and a computer and monitor that receive, process, and display data. This device is intended for use in women with a previous preterm delivery to aid in the detection of preterm labor.



(b) *Classification*. Class II (special controls); guidance document (Class II Special Controls Guidance for Home Uterine Activity Monitors).

Dated: 1/31/01

January 31, 2001.

Linda S. Kahan,
Deputy Director for Regulations Policy,
Center for Devices and Radiological Health.

[FR Doc. 01–????? Filed ??–??–01; 8:45 am]

BILLING CODE 4160–01–S